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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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LISA A. HAILE, Ph.D.
ATTORNEY FOR INTEL CORPORATION
GRAY CARY WARE & FREIDENRICH LLP
4365 Executive Drive, Suite 1100
San Diego, CA 92121-2133

EXAMINER

WILDER, CYNTHIA B

ART UNIT PAPER NUMBER

1637

DATE MAILED: 09/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/672,149

Applicant(s)

CHAN ET AL.

Examiner

Cynthia B. Wilder, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 January 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) 1-25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 26-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 1/31/05, 9/22/04,
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-25, drawn to a method of determining sequence of a nucleic acid, classified in class 435, subclass 6.
 - II. Claims 26-30, drawn to an apparatus, classified in class 435, subclass 287.2.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions II and I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the process could be practiced using the apparatus of Group II or by hand. Further the apparatus can be used for any method in which detection is performed with flow through cells, ranging from oligonucleotide synthesis to nucleic acid sequencing to detection by PCR amplification.

Searching the inventions of Groups I and II together would impose serious search burden.

The inventions of Groups I and II have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for the apparatus and the method of characterizing a nucleic acid are not coextensive because prior art, which may teach the apparatus, may not necessarily be applicable to the method of characterizing a nucleic acid. Moreover, even if the apparatus were known, the method of characterizing a nucleic acid using

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the device may be novel and unobvious in view of the preamble and active steps. The different inventions are patentably distinct requiring different fields of search.

3. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper. Also, because these inventions have acquired a separate status in the art as shown by their different classification and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

4. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. 103(b)", 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP 804.01.

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5. During a telephone conversation with Lisa Haille on September 13, 2005 a provisional election was made with traverse to prosecute the invention of Group II, claims 26-30. Affirmation of this election must be made by applicant in replying to this Office action. Claims 1-25 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claim 27 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(a) Claim 27 is indefinite at the recitation of "capable of" because it cannot be determine whether the limitation after "capable of" is a property of the apparatus or a separate entity. It is suggested amending the claim to recite positive, active language by changing " is capable of detecting" to "detects" or some other positive language as supported by the specification as originally filed.

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(b) Claims 29 and 30 are indefinite and lack proper antecedent basis at the recitation of "The apparatus of claim 20" because claim 20 from which they depend do not recite "an apparatus" but recites "a method". Further the claim 20 has been withdrawn from consideration as being drawn to a non-elected invention. Clarification is required.

Claim Rejections - 35 USC § 102(e)

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. Claims 26, 27 and 29-30 are rejected under 35 U.S.C. 102(e) as being anticipated by Su et al (Pub No. US 2003/0186240 A1, October 2, 2003, filing date March 14, 2002).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Regarding claim 26, Su et al teach an apparatus comprising: a reaction chamber, a first channel in fluid communication with the reaction chamber, a second channel in fluid communications with the first channel; a multiplicity of nanoparticles packed into the second

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channel and a Raman detector operably coupled to the nanoparticle packed channel (see figure 2 and paragraphs 0068 to 0077).

Regarding claim 27, Su et al teach the apparatus of claim 26, wherein the apparatus is capable of detecting single nucleotide molecules (see paragraph 0070).

Note* For the purposes of application of prior art, the claims 29 and 30 are being interpreted by the Examiner as being dependent from the claim 26, which recited an apparatus. Regarding claim 29 and 30, Su et al teach the apparatus of claim 26, wherein the first channel is a microfluidic channel and the second channel is a nanochannel or microchannel (see figure 2 and paragraphs 0068-0077). Therefore, Su et al meets the limitations of claims 26, 27 and 29-30.

11. Claims 26-27 and 29-30 are rejected under 35 U.S.C. 102(e) as being anticipated by Shipwash (2002/0058273 A1, effective filing date August 10, 2000). Regarding claim 26, Shipwash teaches an apparatus comprising a reaction chamber a first channel in fluid communication with the reaction chamber; a second channel in fluid communication with the first channel; a multiplicity of nanoparticles packed in the second channel and a detector coupled to the nanoparticle packed channel, wherein said detector is a Raman detector (figure 14 and paragraphs (see paragraphs 0066, 0167, 0174, 0425, Example 15).

Regarding claim 27, Shipwash teaches the apparatus of claim 26, wherein the apparatus is capable of detecting single nucleotide (0254 and 0255).

Note* For the purposes of application of prior art, the claims 29 and 30 are being interpreted by the Examiner as being dependent from the claim 26, which recited an apparatus. Regarding claim 29 and 30, Shipwash teaches the apparatus of claim 26, wherein the first

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channel is a microfluidic channel and the second channel is a nanochannel or microchannel (see figure 14 and paragraph 0210 and 0425). Therefore, Shipwash meets the limitations of claims 26, 27 and 29-30.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

14. Claims 26-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dorre et al (Bioimaging, vol. 5, pages 139-152, 1997) in view of Dinh (Trends in analytical Chemistry, Vol. 17, nos. 8-9, pages 557-582). Regarding claim 26, Dorre et al teach an apparatus comprising a reaction chamber; a first channel in fluid communications with the reaction chamber, a second channel in fluid communication with the first channel, a multiplicity of nanoparticles packed in the second channel and a detector coupled to the nanoparticle packed

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channel (see section 2.3, pages 142-145). Dorre et al differs from the instant invention in that the reference does not teach wherein the detector is a Raman detector.

Dinh provides a teaching of the use of Raman detectors coupled to nanostructures. Dinh discloses that it has been observed that enormous or unusually strong enhanced Raman scattering signal can occur with nucleic acid molecules being adsorbed on nanoparticle-coated surface (see page 557, "Introduction"). Dinh further teaches that surfaced enhance Raman spectroscopies have a number of important advantages for chemical sensing. Dinh states that first, surface enhanced Raman spectroscopies provides important information related to surface adsorption processes; secondly, the technique allows investigation of new problems, such as characterization and dynamics of adsorbed layers at electrodes, conformation changes and charge-transfer kinetics upon adsorption of organic molecules on colloidal metal particles; and thirdly, at room temperature, Raman spectroscopy can provide an analytical tool having figures of merit that complement luminescence and is well known for its high selectivity. Therefore, in view of the teaching of Dinh, one of ordinary skill in the art at the time of the claimed invention would have been motivated to modify the apparatus of Dorre to encompass a Raman detector rather than a CCD detector coupled to the nanochannel. One of ordinary skill in the art at the time of the claimed invention would have been motivated to do so for the numerous advantages taught by Dinh which includes highly enhanced Raman scattering signal when the nucleic acid is contacted with the nanoparticle-coated surface, high selectivity and increase information system concerning surface adsorption processes and/or problems associated with adsorption or conformational changes.

Regarding claim 27, Dorre teaches the apparatus of claim 26, wherein the apparatus is capable of detecting single nucleotide molecules (section 2.3).

Regarding claim 28, Dorre teaches the apparatus of claim 26, further comprising a first and second electrode to move the nucleotides for the different channels (section 2.3).

Note* For the purposes of application of prior art, the claims 29 and 30 are being interpreted by the Examiner as being dependent from the claim 26, which recited an apparatus. Regarding claims 29 and 30, Dorre teaches the apparatus of claim 26, wherein the first channel is a microfluidic channel and the second channel is a nanochannel or microchannel (section 2.3).

Double Patenting

15. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

16. Claims 26, 27, 29-30 are provisionally rejected under the judicially created doctrine of double patenting over claims 24, 25, 27-30 of copending Application No. 10/099287). An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the

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reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F. 2d 887, 225 USPQ 645 (fed. Cir. 1985). Thus, the claims 26, 27, 29-30 of the instant invention falls entirely within the scope of the claims 24, 25, 27-30 of copending application 10/099287 . As the court stated in *In re Goodman*, 29 USPQ2d 2010 (CAFC 1993), " a second application-- "containing a broader claim, more generical in its character than the specific claim in the prior patent"-- typically cannot support an independent valid patent. *Miller*, 151, U.S. at 198; See *Stanley*, 214 F.2d at 153. Thus, the generic invention, as noted above is "anticipated" by the species of the patented invention. Cf., *Titanium metal corp. v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985) (holding that an earlier species disclosure in the prior art defeats any generic claims). This court's predecessor has held that, without a terminal disclaimer, the species claims preclude issuance of the generical application. "*In re Van Ornum*, 686 F.2d 937, 944, 214 USPQ 761, 767 (CCPA 1982); *Schneller*, 397 F.2d at 354".

This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

Conclusion

17. No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia B. Wilder, Ph.D. whose telephone number is (571) 272-0791. The examiner works a flexible schedule and can be reached by phone and voice mail. Alternatively, a request for a return telephone call may be emailed to cynthia.wilder@uspto.gov. Since email communications may not be secure, it is suggested that

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information in such request be limited to name, phone number, and the best time to return the call.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.


CYNTHIA WILDER
PATENT EXAMINER
9/15/2005